UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE LUMIFY	Civil Action No. 21-16766 (RK) (RLS) (CONSOLIDATED) *Document Electronically Filed*

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3 and the Stipulation Regarding Schedule Between Plaintiffs and Defendants (D.I. 102), Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") and Defendants Slayback Pharma LLC, Slayback Pharma India LLP, Dr. Reddy's Laboratories S.A., and Dr. Reddy's Laboratories Inc. (collectively, "Defendants"), submit this Joint Claim Construction and Prehearing Statement for U.S. Patent No. 11,596,600 ("the '600 patent").

I. Background

In this Hatch-Waxman patent action, Plaintiffs assert infringement of claims 12 and 28–30 of the '600 patent (the "Asserted Claims") against Defendants based on, *inter alia*, Defendants' submission of ANDA No. 216361 to the FDA seeking approval for generic versions of Plaintiffs' Lumify® ophthalmic solution/drops (brimonidine tartrate, 0.025%).

In compliance with Local Patent Rules 4.2(a)–(b), the parties exchanged preliminary claim constructions and identified intrinsic and extrinsic evidence in support of their proposed preliminary constructions for the '600 patent on October 20, 2023. In compliance with Local Patent Rule 4.2(c), the parties identified all intrinsic and extrinsic evidence that each party intends to rely on to oppose any other party's proposed preliminary constructions for the '600 patent on

October 27, 2023. In compliance with Local Patent Rule 4.2(d), counsel for the parties met and conferred for the purposes of narrowing the issues and preparing the Joint Claim Construction and Prehearing Statement on October 31, 2023. There are currently 4 claim terms from the '600 patent requiring the Court's consideration.

II. Local Patent Rule 4.3

A. Construction of Claim Terms on which the Parties Agree

Local Patent Rule 4.3(a) requires the parties to identify the constructions of those terms on which the parties agree. At present, the parties have not agreed on the meaning of any term or phrase identified for construction by the Court from the Asserted Claims of the '600 patent.

The parties are separately negotiating staying all deadlines in connection with the claims and defenses solely for U.S. Patent No. 8,293,742 ("the '742 patent") pending the resolution of *Eye Therapies, LLC v. Slayback Pharma LLC*, Appeal No. 23-2173 ("'742 patent appeal"). Thus, the parties do not believe it is necessary to brief any claim construction issues for the '742 patent at this time.

B. Each Party's Proposed Construction of Each Disputed Term

In accordance with Local Patent Rule 4.3(b), the parties identify in Exhibit A each disputed term or phrase from the asserted claims of the '600 patent and their respective proposed constructions for those terms or phrases. Exhibit A also identifies the intrinsic and extrinsic evidence on which each side intends to rely in support of its proposed constructions or to oppose the other sides' proposed constructions.

Although Defendants believe there is a need for the term "about 0.025%" to be construed, the Parties believe that the construction of "about 0.025%" for the '600 patent should be deferred pending the resolution of the '742 patent appeal given that Eye Therapies is appealing the Board's construction of the same phrase for the '742 patent. To the extent necessary, the Parties reserve

the right to request the Court's construction of "about 0.025%" if issues arise in the litigation where construction is needed.

C. Identification of Significant and Dispositive Claim Terms

Local Patent Rule 4.3(c) requires the parties to identify the constructions that will be most significant to the resolution of the case and whether any of the disputed terms will be case or claim dispositive or substantially conducive to promoting settlement.

Plaintiffs' position: Plaintiffs do not believe any of the disputed terms or phrases are more significant than any others and do not believe that the construction of any of the disputed terms or phrases will be case or claim dispositive or substantially conducive to promoting settlement. Plaintiffs disagree that any claim terms identified by Defendants are indefinite. Plaintiffs believe that the resolution of any indefiniteness issues raised by Defendants should be deferred until trial.

Defendants' position: Defendants have identified two claim terms that are not amenable to any construction. Resolution of the indefiniteness issues raised by Defendants for these terms at this stage could be claim dispositive for two Asserted Claims.

D. Anticipated Length of Time Necessary for the Claim Construction Hearing

In accordance with Local Patent Rule 4.3(d), the parties estimate that the claim construction hearing will require approximately 6 hours (3 hours allocated to Plaintiffs and 3 hours allocated to Defendants).

E. Proposed Witnesses for Claim Construction Hearing and Summary of Testimony and Opinions

In accordance with Local Patent Rule 4.3(e), the parties identify the following as possible witnesses for the claim construction hearing:

Plaintiffs expect to call Dr. Robert J. Noecker, Dr. William B. Trattler, Dr. Stephen G. Davies, Dr. Robert O. Williams III, and/or Dr. W. Daniel Stamer as expert witnesses in connection

with the disputed claim terms listed in Exhibit A, to testify as to the definition of a person of ordinary skill in the art at the relevant time, and to explain the meaning of the claims, including the disputed claim terms/phrases, as they would be understood by a person of ordinary skill in the art.

Defendants expect to call Drs. Paul A. Laskar, John Galanis, and/or Radojka Savic as expert witnesses in connection with the disputed claim terms listed in Exhibit A, to testify as to the definition of a person of ordinary skill in the art at the relevant time, and to explain the meaning of the claims, including the disputed claim terms/phrases, as they would be understood by a person of ordinary skill in the art.

Dated: November 3, 2023

s/ William P. Deni, Jr.

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EXHIBIT A

The Parties' Proposed Constructions and Evidence Regarding Disputed Claim Terms and Phrases

Disputed Claim Term/Phrase[1]	Plaintiffs' Proposed Claim Construction[2] and Evidence[3] [4]	Defendants' Proposed Claim Construction and Evidence[5]
"[human] in need of said reduction of eye redness" (Claims 12, 28-30)	**Construction:** Plaintiffs propose that this phrase, as it is used in the claims of the '600 patent, should be given its plain and ordinary meaning, as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which a person of ordinary skill in the art would have understood to mean "a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction." **Evidence:** The '600 patent, the claim language, and prosecution history, including references and declarations cited or submitted therein. *See, e.g.*, '600 patent at 1:23, 2:27-46, 2:50-55, 4:41-45, 4:62-5:6, 5:43-50, 7:24-41, 9:46-60, 10:21-26, 12:36-41, 13:16-20, 13:8-12, 14:21-46, 14:59-61, Examples 1, 4, and 5.	**Construction:** "having ocular hyperemia" **Evidence:** *See, e.g.*, '600 patent and file history generally. *See also, e.g.*, '600 patent at claim 1. '600 patent at 1:20–25. '600 patent at 12:35–13:5. '600 patent at 14:41–44. *Conjunctival hyperemia*, NATIONAL LIBRARY OF MEDICINE. P.J. Murphy et al., *How red is a white eye? Clinical grading of normal conjunctival hyperaemia*, 21 EYE 633–38 (2007).

[1] For the disputed claim terms/phrases, any text appearing in brackets is not part of the disputed claim term/phrase identified by the Parties on October 4, 2023, but is included to provide context for the disputed claim term/phrase.

[2] Plaintiffs contend that the claims, including their terms and phrases, require no special construction and should be given their plain and ordinary meaning as understood by the person of ordinary skill in the art at the time of invention, consistent with the intrinsic record. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-14 (Fed. Cir. 2005) (en banc). To the extent the Court determines that any of the terms and phrases identified requires construction, Plaintiffs propose the following constructions.

[3] Plaintiffs reserve the right to rely on all intrinsic evidence, including the asserted patents and their complete file history.

[4] For each cited reference, Plaintiffs reserve the right to rely on any portion of the reference.

[5] Defendants reserve the right to rely on all intrinsic evidence, including the asserted patents and their complete file history. Defendants further reserve the right to rely on any portion of the reference.

	The '600 patent file history, including, but not limited to, the November 4, 2022 Amendments and Applicant's Arguments and Remarks. Expert testimony from Dr. Robert J. Noecker, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Ophthalmic Consultants of Connecticut with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "human in need of said reduction of eye redness" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction," and to rebut expert testimony offered by Defendants. Expert testimony from William B. Trattler, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Center for Excellence in Eye Care with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood	H. Cronau et al., *Diagnosis and Management of Red Eye in Primary Care*, 81(2) AM. FAMILY PHYSICIAN 137–144 (2010). B. Tarlan and H. Kiratli, *Subconjunctival hemorrhage: risk factors and potential indicators*, 2013:7 CLINICAL OPHTHALMOLOGY 1163–70 (June 11, 2013). Defendants may submit expert testimony of Dr. John Galanis in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants reserve the right to rely on any document cited in Plaintiffs' L. Pat. R. 4.2(a)–(c) disclosures to support Defendants' proposed construction or rebut Plaintiffs' proposed construction.

	the phrase "human in need of said reduction of eye redness" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction," and to rebut expert testimony offered by Defendants. Expert testimony from W. Daniel Stamer, a Joseph A.C. Wadsworth Distinguished Professor of Ophthalmology specializing in the identification and validation of novel drug targets to facilitate the development of the next generation of treatments for ocular hypertension and glaucoma, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "human in need of said reduction of eye redness" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "a human having ocular hyperemia, where such hyperemia is reduced by vasoconstriction," and to rebut expert testimony offered by Defendants. Patents and applications in the priority chain of the '600 patent, for example, U.S. Provisional	

	Application Nos. 61/207,481, 61/203,120, 61/192,777, and 61/137,714. Other related patents or applications in the same families as the '600 patent, including, for example, U.S. Patent Nos. 8,293,742, 9,259,425, and U.S. Patent Application Publication Nos. 2010/0029659, 2010/0028266, 2010/0029662, and 2010/0029663. Plaintiffs' contentions, IND, and NDA. *See, e.g.*, BAU-LUM00000001-BAU-LUM00061135. Defendants' Paragraph IV Notice Letter, contentions, and ANDA. Documents and evidence Eye Therapies, LLC and Petitioner submitted in IPR2022-00142, including the papers, declarations of Dr. Robert J. Noecker, Dr. Robert O. Williams III, and Dr. Stephen G. Davies, including their opinions and the exhibits referenced therein as they bear on and support Plaintiffs' proposed construction for this phrase, all of which are incorporated by reference in their entirety as if set forth herein. Documents and evidence Petitioner submitted in IPR2022-00142, including Petitioner's papers, exhibits, and the declarations of Dr. Neal A. Sher and Dr. Paul A. Laskar. Transcripts from the depositions of Dr. Neal A. Sher and Dr. Paul A. Laskar in connection with IPR2022-00142 and the transcript from the oral hearing in IPR2022-00142 as they relate to Plaintiffs' proposed construction.	

	All evidence identified by Defendants.	
"about 0.025%" (Claim 12)	**Construction:** Plaintiffs propose that this phrase, as it is used in claim 1 of the '600 patent, should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which in the context of the pharmaceutical arts and substantiated by the standards in the field a person of ordinary skill in the art would have understood to mean "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%." **Evidence:** The '600 patent, the claim language, and prosecution history, including references and declarations cited or submitted therein. *See, e.g.*, '600 patent at 2:20-46, 2:50-55, 3:32-36, 4:11-13, 4:40-45, 4:62-5:4, 5:51-61, 5:65-67, 6:8-10, 6:15-21, 6:25-26, 6:52-54, 7:19-33, 8:19-30, 8:49-9:3, 9:10-12, 9:32-34, 9:38-42, 9:46-60, 10:4-6, 10:14-18, 10:21-35, 11:14-16, 11:27-31,11:38-39, 11:43-65, 12:29-41, 13:16-23, 13:65-67, 14:39-40, 14:60-61, 19:20-23, 20:24-29, 21:47-49, Example 3, Figures 2, 4A-E, and 6, claims 2 and 3. Expert testimony from Dr. Robert J. Noecker, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Ophthalmic Consultants of Connecticut with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat	**Construction:** "approximately 0.025%, including 0.03%" **Evidence:** *See, e.g.,* '600 patent and file history generally. *See also, e.g.*, '600 patent at abstract. '600 patent at figures 2, 4E, 6. '600 patent at 2:7–19. '600 patent at 3:17–20. '600 patent at 3:43–46. '600 patent at 3:65–67. '600 patent at 4:8–9. '600 patent at 9:32–34. '600 patent at 13:16–19. '600 patent at 14:37–39. '600 patent at 20:24–28. '600 patent at 20:57–58. '600 patent at claim 1.

	ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the term "about 0.025%" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, as substantiated by the standards in the pharmaceutical field, to have its plain and ordinary meaning of "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%," and to rebut expert testimony offered by Defendants. Expert testimony from William B. Trattler, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Center for Excellence in Eye Care with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art regarding ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the term "about 0.025%" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008,as substantiated by the standards in the pharmaceutical field, to have its plain and ordinary meaning of "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%," and to rebut expert testimony offered by Defendants.	U.S. Provisional Application No. 61/207,481 ("the '481 provisional") at figure 4. '481 provisional at 68. Defendants may submit expert testimony of Dr. Paul A. Laskar in connection with claim construction on substance including, , but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may submit expert testimony of Dr. John Galanis in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may also rely on documents and evidence submitted in IPR2022-00142, including the papers, declarations, any exhibits cited within the papers and declarations, and the Final Written Decision, all of which are incorporated by reference in their entirety as if set forth herein. *See, e.g.*, Ex. 1048, Declaration of Paul Laskar, Ph.D in Support of

	Expert testimony from Dr. Robert O. Williams, Johnson & Johnson Centennial Chair and Professor in the Division of Molecular Pharmaceutics and Drug Delivery at the University of Texas at Austin College of Pharmacy in Austin, Texas with more than 40 years of experience, who will provide testimony regarding the background technology and state of the art with respect to pharmaceutical formulation and development, what the requisite credentials and experience of a person of ordinary skill would include, how an ordinary skilled artisan would have understood the term "about 0.025%" in the context of the intrinsic evidence (including the claim language, the patent specification, and the prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, as substantiated by the standards in the pharmaceutical field, to have its plain and ordinary meaning of "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%," and to rebut expert testimony offered by Defendants. Expert testimony from Dr. Stephen G. Davies, Chemistry Emeritus at the University of Oxford, and Extraordinary Lecturer in Chemistry at New College, Oxford, England with more than 45 years of experience, who will provide testimony regarding the background technology and state of the art with respect to medicinal chemistry, what the requisite credentials and experience of a person of ordinary skill would include, how an ordinary skilled artisan would have understood the term "about 0.025%" in the context of the intrinsic evidence (including the claim language, the patent specification, and the prosecution history) and any extrinsic evidence based on the perspective of one	Petitioner's Reply; Ex. 1055, U.S. Pharmacopeia 28-National Formulary 23 (2005); Ex. 2026, 65 Fed. Reg. 83,041 (Dec. 29, 2000). Defendants reserve the right to rely on any document cited in Plaintiffs' L. Pat. R. 4.2(a)–(c) disclosures to support Defendants' proposed construction or rebut Plaintiffs' proposed construction.

	skilled in the art as of August 1, 2008, as substantiated by the standards in the pharmaceutical field, to have its plain and ordinary meaning of "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%," and to rebut expert testimony offered by Defendants. Expert testimony from W. Daniel Stamer, a Joseph A.C. Wadsworth Distinguished Professor of Ophthalmology specializing in the identification and validation of novel drug targets to facilitate the development of the next generation of treatments for ocular hypertension and glaucoma, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "about 0.025%" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%," and to rebut expert testimony offered by Defendants. Plaintiffs' expert testimony will be consistent with Dr. Williams' and Dr. Noecker's declarations submitted in IPR2022-00142, the testimony will explain that the phrase "about 0.025%" should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and	

	file history, which in the context of the pharmaceutical arts and substantiated by the standards in the field a person of ordinary skill in the art would understand means "not more than plus or minus 10% of 0.025%, *i.e.*, 0.0225% to 0.0275%." *See, e.g.*, Noecker Decl., ¶¶ 94-95, 106-122 (BAU-LUM00064322-23; BAU-LUM00064330-37); Williams Decl. (IPR2022-00142, EX-2021), ¶¶ 36-50 (BAU-LUM00064501-07); Davies Decl., ¶ 25 (BAU-LUM00064790). Patents and applications in the priority chain of the '600 patent, for example, U.S. Provisional Application Nos. 61/207,481 ("'481 provisional"), 61/203,120, 61/192,777, and 61/137,714. *See, e.g.*, '481 provisional at 68, 111, and 121. Other related patents or applications in the same families as the '600 patent, including, for example, U.S. Patent Nos. 8,293,742, 9,259,425, and U.S. Patent Application Publication Nos. 2010/0029659, 2010/0028266, 2010/0029662, and 2010/0029663. Plaintiffs' contentions, IND, and NDA. *See, e.g.*, BAU-LUM00000001-BAU-LUM00061135. Defendants' Paragraph IV Notice Letters, contentions, and ANDAs. Documents and evidence Eye Therapies, LLC and Petitioner submitted in IPR2022-00142, including the papers, declarations of Dr. Robert J. Noecker, Dr. Robert O. Williams III, and Dr. Stephen G. Davies, including their opinions and the exhibits referenced therein as they bear on and support	

	Plaintiffs' proposed construction for this phrase, all of which are incorporated by reference in their entirety as if set forth herein. *See, e.g.*, Noecker Decl., ¶¶ 94-95, 106-122 (BAU-LUM00064322-23; BAU-LUM00064330-37); Sher Dep. Tr. (Aug. 10, 2022) at 98:24-100:5 (BAU-LUM00069842); Soparkar (IPR2022-00142, EX-2182) at 4-5 (BAU-LUM00070033-34); Williams Decl., ¶¶ 36-50 (BAU-LUM00064648-54);USP 32 General Notices and Requirements "Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia" (IPR2022-00142, EX-2025) at 4, 8 (BAU-LUM00065226, 00065230); 65 Fed. Reg. 83,041 (Dec. 29, 2000) (IPR2022-00142, EX-2026) at 83044-83045 (BAU-LUM00065238-39); Skwietczynski, "Chapter 2 - Analysis of Medicinals", Remington Essentials of Pharmaceuticals (IPR2022-00142, EX-2027) at 10-11 (BAU-LUM00065264-65); "Legal Recognition - Standards Categories", The United States Pharmacopeia Convention (IPR2022-00142, EX-2029) at 1 (BAU-LUM00065292); Davies Decl., ¶ 25 (BAU-LUM00064790); Laskar Dep. Tr. (Aug. 4, 2022) at 51:1-12 (BAU-LUM00070160); Laskar Dep. Tr. (Jan. 18, 2023) at 128:24-130:3, 134:11-18 (BAU-LUM00070335-337, BAU-LUM00070341). Documents and evidence Petitioner submitted in IPR2022-00142, including Petitioner's papers, exhibits, and the declarations of Dr. Neal A. Sher and Dr. Paul A. Laskar. Transcripts from the depositions of Dr. Neal A. Sher and Dr. Paul A. Laskar in connection with IPR2022-00142 and the transcript from the oral hearing in IPR2022-00142.	

	All evidence identified by Defendants.	
"as the sole active ingredient" (Claims 12, 28-30)	**Construction**: Plaintiffs propose that this phrase, as it is used in claim 1 of the '600 patent, should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which a person of ordinary skill in the art would have understood to mean "[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia." **Evidence**: The '600 patent, the claim language, and prosecution history, including references and declarations cited or submitted therein. *See, e.g.*, '600 patent at 6:15-28, 7:24-41, 8:19-25, 8:49-9:3, 9:46-60, 10:21-35, 16:57-17:3 *compare and contrast with* 7:19-23, 8:26-30, 9:38-42, 10:14-18; Examples 1 and 4. The '600 patent file history, including, but not limited to, the November 4, 2022 Amendments and Applicant's Arguments and Remarks. Expert testimony from Dr. Robert J. Noecker, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Ophthalmic Consultants of Connecticut with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the	**Construction:** "without any other active ingredient in the ocular drop" **Evidence:** *See, e.g.,* '600 patent and file history generally. *See also, e.g.*, '600 patent at claim 1. '600 patent at 6:15–21. '600 patent at 6:22–28. '600 patent at 7:19–23. '600 patent at 7:24–33. '600 patent at 7:34–41. '600 patent at 8:19–25. '600 patent at 8:26–35. '600 patent at 8:49–59. '600 patent at 8:60–9:3. '600 patent at 9:4–12. '600 patent at 9:38–42. '600 patent at 9:46–52. '600 patent at 9:53–60.

	art would include, how an ordinarily skilled artisan would have understood the phrase "as the sole active ingredient" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia," and to rebut expert testimony offered by Defendants. Expert testimony from William B. Trattler, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Center for Excellence in Eye Care with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "as the sole active ingredient" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "[administering brimonidine] as the only active ingredient to affirmatively reduce redness in a person having ocular hyperemia," and to rebut expert testimony offered by Defendants. Patents and applications in the priority chain of the '600 patent, for example, U.S. Provisional	'600 patent at 10:14–18. '600 patent at 10:21–26. '600 patent at 10:27–35. '600 patent at 16:57–63. '600 patent at 16:14–17:4. Defendants may submit expert testimony of Dr. Paul A. Laskar in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may submit expert testimony of Dr. John Galanis in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may also rely on documents and evidence submitted in IPR2022-00142, including the papers, declarations, and Final

	Application Nos. 61/207,481, 61/203,120, 61/192,777, and 61/137,714. Other related patents or applications in the same families as the '600 patent, including, for example, U.S. Patent Nos. 8,293,742, 9,259,425, and U.S. Patent Application Publication Nos. 2010/0029659, 2010/0028266, 2010/0029662, and 2010/0029663. Plaintiffs' contentions, IND, and NDA. *See, e.g.*, BAU-LUM00000001-BAU-LUM00061135. Defendants' Paragraph IV Notice Letter, contentions, and ANDA. Documents and evidence Eye Therapies, LLC and Petitioner submitted in IPR2022-00142, including the papers, declarations of Dr. Robert J. Noecker, Dr. Robert O. Williams III, and Dr. Stephen G. Davies, including their opinions, and the exhibits referenced therein as they bear on and support Plaintiffs' proposed construction for this phrase, all of which are incorporated by reference in their entirety as if set forth herein. *See, e.g.*, Noecker Decl., ¶¶ 103 n.9, 173, 244 (BAULUM00064327-328, BAULUM00064358, BAU-LUM00064385); Sher Dep. Tr. (Jan. 27, 2023) at 12:25-13:7, 18:10-21:8, 22:24-23:13, 41:17-42:4 (BAU-LUM00070400-401, BAULUM00070406-411, BAULUM00070429-430); Dean (IPR2022-00142, EX-1007) at 2:22-29, 2:51-57, 3:29-34 (SLAY-BRIM 0005647-48); Norden 2002 at 4-5 (SLAY-BRIM0005642-43); IPR2022-00142 EX-1002, EX-1003, EX-1004.	Written Decision, all of which are incorporated by reference in their entirety as if set forth herein. Defendants reserve the right to rely on any document cited in Plaintiffs' L. Pat. R. 4.2(a)–(c) disclosures to support Defendants' proposed construction or rebut Plaintiffs' proposed construction.

	Documents and evidence Petitioner submitted in IPR2022- 00142, including Petitioner's papers, exhibits, and the declarations of Dr. Neal A. Sher and Dr. Paul A. Laskar. Transcripts from the depositions of Dr. Neal A. Sher and Dr. Paul A. Laskar in connection with IPR2022-00142 and the transcript from the oral hearing in IPR2022-00142 as they relate to Plaintiffs' proposed construction. References disclosing the use of other drugs during the dosing protocol for radial keratotomy surgery, including, for example: M. Bashour, Radial Keratotomy for Myopia Correction, https://emedicine.medscape.com/article/1222168-print (April 18, 2017); W.J. Jory, Radial Keratotomy: 500 Consecutive Cases, Eye (1989) 3, 663-671; K.R. Mehta, Radial Keratotomy, Indian J Ophthalmol 1990; 38:124-131; 2004-2008 Provider Synergies, L.L.C., Ophthalmic NSAIDs Review (Sept. 9, 2008); J.B. Robin, Radial Keratotomy: Procedures, Indian J Ophthalmol 1990; 38:103-106; R. Yee, Analgesic Efficacy and Safety of Nonpreserved Ketorolac Tromethamine Ophthalmic Solution Following Radial Keratotomy, Am J Ophthalmol 1998; 125:472-480.	

	All evidence identified by Defendants.	
"[induces a] low incidence of rebound hyperemia [in the eye of the human subject]" (Claims 29-30)	**Construction:** Plaintiffs propose that this phrase, as it is used in claims 4 and 25 of the '600 patent, should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which a person of ordinary skill in the art would have understood to mean "reduces the likelihood of developing rebound hyperemia in the eye of a human subject." **Evidence:** The '600 patent, the claim language, and prosecution history, including references and declarations cited or submitted therein. *See, e.g.*, '600 patent at 2:4-46, 3:49-64, 4:40-5:25, 8:41-43, 10:7-13, 13:28-33, 14:21-29, 15:14-24, 15:54-57, 16:10-15, 19:19-28, 19:43-64, 20:5-30, FIGS. 1-3, 5B-5C, and 6; Example 1, Example 2, Example 4, and Example 5. The '600 patent file history, including, but not limited to, the November 4, 2022 Amendments and Applicant's Arguments and Remarks. Expert testimony from Dr. Robert J. Noecker, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Ophthalmic Consultants of Connecticut with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the	**"low" is indefinite:** Neither the specification nor the prosecution history provides guidance as to the metes and bounds of the term "low." A person of ordinary skill in the art reading the specification and prosecution history would not, with reasonable certainty, be able to ascertain the meaning of the claim limitation "low incidence of rebound hyperemia." **Construction:** "incidence of rebound hyperemia" means "percentage of patients that experience rebound hyperemia over a period of time" **Evidence:** *See, e.g.*, '600 patent and file history generally. *See also, e.g.*, '600 patent at claims 4, 25. '600 patent at 2:4–10. '600 patent at 4:8–10. '600 patent at 4:31–37. '600 patent at 4:40–5:25. '600 patent at 4:62–5:6. '600 patent at 13:28–30. '600 patent at 15:13–15.

	art would include, how an ordinarily skilled artisan would have understood the phrase "induces a low incidence of rebound hyperemia in the eye of the human subject" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "reduces the likelihood of developing rebound hyperemia in the eye of a human subject," and to rebut expert testimony offered by Defendants. Expert testimony from William B. Trattler, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Center for Excellence in Eye Care with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "induces a low incidence of rebound hyperemia in the eye of the human subject" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "reduces the likelihood of developing rebound hyperemia in the eye of a human subject," and to rebut expert testimony offered by Defendants. Expert testimony from W. Daniel Stamer, a Joseph A.C. Wadsworth Distinguished Professor	'600 patent at 15:54–57. '600 patent at 20:5–30. '600 patent at 21:57–22:19. '600 patent at FIGs. 5A-C. S. Tenny and S. Boktor, *Incidence*, STATPEARLS. B. Roe and H. Doll, *Prevalence and incidence*, 9 J. OF CLINICAL NURSING 178–88 (1995). *Incidence*, Center for Disease Control and Prevention – National Center for Health Statistics. M. Porta (ed.), A DICTIONARY OF EPIDEMIOLOGY (6 ed.), (May 23, 2014). D. Dabelea, *Incidence of Diabetes in Youth in the the United States*, 297(24) JAMA 2716–25 (2007). A.W.F. Edwards, *Likelihood*, In: J. Eatwell, J. et al. (eds), *Time Series and Statistics* (1990). J.T. Whitson et al., *The Safety and Intraocular Pressure-Lowering Efficacy of Brimonidine Tartrate 0.15% Preserved with Polyquaternium-1*, 113 OPHTHALMOLOGY 1333–39 (2006). Defendants may submit expert testimony of Dr. Paul A. Laskar in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and

	of Ophthalmology specializing in the identification and validation of novel drug targets to facilitate the development of the next generation of treatments for ocular hypertension and glaucoma, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "induces a low incidence of rebound hyperemia in the eye of the human subject" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "reduces the likelihood of developing rebound hyperemia in the eye of a human subject," and to rebut expert testimony offered by Defendants. Patents and applications in the priority chain of the '600 patent, for example, U.S. Provisional Application Nos. 61/207,481, 61/203,120, 61/192,777, and 61/137,714. Other related patents or applications in the same families as the '600 patent, including, for example, U.S. Patent Nos. 8,293,742, 9,259,425, and U.S. Patent Application Publication Nos. 2010/0029659, 2010/0028266, 2010/0029662, and 2010/0029663. Plaintiffs' contentions, IND, and NDA. *See, e.g.*, BAU-LUM00000001-BAU-LUM00061135.	the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may submit expert testimony of Dr. John Galanis in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may submit expert testimony of Dr. Radojka Savic in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants reserve the right to rely on any document cited in Plaintiffs' L. Pat. R. 4.2(a)–(c) disclosures to support Defendants' proposed construction or rebut Plaintiffs' proposed construction.

	Defendants' Paragraph IV Notice Letter, contentions, and ANDA. References indicating that prior art redness relievers caused a high incidence of rebound hyperemia, for example: C. Soparkar et al., Acute and Chronic Conjunctivitis Due to Over-the-counter Ophthalmic Decongestants, Arch Ophthalmol. 1997;115:34-38 (BAU-LUM00070030-BAU-LUM00070036); S. L. Spector and M. B. Raizman, Conjunctivitis medicamentosa, J Allergy Clin Immunol, 1994;94:134-6 (BAU-LUM00070036-BAU-LUM00070039). All evidence identified by Defendants.	
"[to] improve the aesthetic appearance of the eye [to which the ocular drop is administered]" (Claim 30)	**Construction:** Plaintiffs propose that this phrase, as it is used in claim 15 of the '600 patent, should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art at the time of invention consistent with the intrinsic record, including the specification and file history, which a person of ordinary skill in the art would have understood to mean "to improve the aesthetic appearance of the eye by reducing the appearance of eye redness that is excessive or is attributable to non-infectious conjunctival hyperemia caused by, for example, lack of sleep, consumption of alcohol, or other noninfectious causes."	**Indefinite:** Neither the specification nor the prosecution history provides guidance as to the metes and bounds of the term "improve the aesthetic appearance of said eye." A person of ordinary skill in the art reading the specification and prosecution history would not, with reasonable certainty, be able to ascertain the meaning of the claim limitation "improve the aesthetic appearance of said eye." **Evidence:** *See, e.g.*, '600 patent and file history generally. *See also, e.g.*,

	Evidence: The '600 patent, the claim language, and prosecution history, including references and declarations cited or submitted therein. *See, e.g.*, '600 patent at 13:3-5, 13:8-15, 14:30-36, 14:41-44. The '600 patent file history, including, but not limited to, the November 4, 2022 Amendments and Applicant's Arguments and Remarks. Expert testimony from Dr. Robert J. Noecker, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Ophthalmic Consultants of Connecticut with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "to improve the aesthetic appearance of said eye to which the ocular drop is administered" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "to improve the aesthetic appearance of the eye by reducing the appearance of eye redness that is excessive or is attributable to non-infectious conjunctival hyperemia caused by, for example, lack of sleep, consumption of alcohol, or other noninfectious causes," and to rebut expert testimony offered by Defendants.	'600 patent at claim 15. '600 patent at 13:3–5. '600 patent at 14:21–40. '600 patent at 14:41–44. Defendants may submit expert testimony of Dr. Paul A. Laskar in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants may submit expert testimony of Dr. John Galanis in connection with claim construction on substance including, but not limited to, the plain and ordinary meaning of this term, the definition of a person of ordinary skill in the art, the state of the art at the time of the invention, and whether a person of ordinary skill in the art would, in light of the specification and the prosecution history, be informed with reasonable certainty about the meaning of this claim term and the scope of the invention. Defendants reserve the right to rely on any document cited in Plaintiffs' L. Pat. R. 4.2(a)–(c) disclosures to support Defendants' proposed construction or rebut Plaintiffs' proposed construction.

	Expert testimony from William B. Trattler, M.D., an ophthalmologist specializing in refractive, corneal and cataract eye surgery at the Center for Excellence in Eye Care with more than 25 years of experience, who will provide testimony regarding the background technology and state of the art with respect to ophthalmic formulations and their administration to treat ocular conditions, what the requisite credentials and experience of a person of ordinary skill in the art would include, how an ordinarily skilled artisan would have understood the phrase "to improve the aesthetic appearance of said eye to which the ocular drop is administered" in the context of the intrinsic evidence (including the claim language, patent specification, and prosecution history) and any extrinsic evidence based on the perspective of one skilled in the art as of August 1, 2008, to have its plain and ordinary meaning of "to improve the aesthetic appearance of the eye by reducing the appearance of eye redness that is excessive or is attributable to non-infectious conjunctival hyperemia caused by, for example, lack of sleep, consumption of alcohol, or other noninfectious causes," and to rebut expert testimony offered by Defendants. Patents and applications in the priority chain of the '600 patent, for example, U.S. Provisional App. No. 61/137,714 at BAU-LUM00063145; U.S. Provisional App. No. 61/192,777 at 2, 19, 25, 38; U.S. Provisional App. No. 61/203,120 at 2, 45. Other related patents or applications in the same families as the '600 patent, including, for example, U.S. Patent Nos. 8,293,742, 9,259,425, and U.S. Patent Application Publication Nos. 2010/0029659, 2010/0028266, 2010/0029662, and 2010/0029663.	

	Plaintiffs' contentions, IND, and NDA. *See, e.g.*, BAU-LUM00000001-BAU-LUM00061135. Defendants' Paragraph IV Notice Letter, contentions, and ANDA. All evidence identified by Defendants.	